PATENT
Docket No. 412692000401

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Jennifer Bushard

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

D. Laksen SIRIMANNE et al.

Serial No.: To Be Assigned

Filing Date: Herewith

For: SUBCUTANEOUS CAVITY MARKING DEVICE AND METHOD

Examiner: To Be Assigned

Group Art Unit: To Be Assigned

PRELIMINARY AMENDMENT

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Prior to examination of this application, please make the following amendments and consider the following remarks:

AMENDMENTS

In the claims:

A clean version of the entire set of pending claims is as follows:

1. (amended) A subcutaneous cavity marking device comprising:

(a) at least one resilient bioabsorbable filler body, and

(b) at least one detectable marker attached to said filler body, wherein at least one of said detectable markers is located at or near a geometric center of said filler body.

2. The device of claim 1 wherein the at least one marker comprises a non-bioabsorbable material.

3. The device of claim 2 wherein the marker comprises a material selected from the group consisting of platinum, iridium, nickel, tungsten, tantalum, gold, silver, rhodium, titanium, alloys thereof, and stainless steel.

4. (amended) The device of claim 1 wherein the at least one marker comprises a bioabsorbable material.

5. (amended) The device of claim 4 wherein the bioabsorbable material comprises a polymer having a radiopaque additive.

6. The device of claim 5 wherein the radiopaque additive is selected from the group consisting of barium-containing compounds, bismuth-containing compounds, powdered tantalum, powdered tungsten, barium carbonate, bismuth oxide, and barium sulfate.

7. The device of claim 1 wherein the at least one marker is radiopaque.

8. The device of claim 1 wherein the at least one body is radiopaque.

9. The device of claim 1 wherein the at least one marker is echogenic.

10. The device of claim 1 wherein the at least one body is echogenic.

11. The device of claim 1 wherein the at least one marker is mammographic.

12. The device of claim 1 wherein the at least one body is mammographic.

13. The device of claim 1 wherein the at least one body is palpable.

14. The device of claim 1 wherein the marker is located within an interior of the at least one body.

15. The device of claim 1 wherein the marker is substantially located within a geometric center of the at least one body.

16. The device of claim 1 additionally comprising a pain killing substance.

17. The device of claim 1 additionally comprising a hemostatic substance.

18. (amended) The device of claim 1 wherein the bioabsorbable filler body comprises a material selected from the group consisting of collagen, regenerated cellulose, synthetic polymers, and synthetic proteins.

19. The device of claim 1 wherein the marker has a form of a sphere.

20. The device of claim 19 wherein the sphere is hollow.

21. The device of claim 1 wherein the marker has a form of a band.

22. The device of claim 1 wherein the marker comprises a suture.

23. The device of claim 1 wherein the marker comprises a wire.

24. The device of claim 1 wherein the marker has a distinguishing mark.

25. The device of claim 1 wherein the marker is fixedly attached to the at least one body.

26. The device of claim 25 wherein the marker is woven to the at least one body.

27. The device of claim 1 wherein the marker is radioactive.

28. The device of claim 1 wherein the at least one body is radioactive.

29. The device of claim 1 wherein the at least one body is substantially spherical.

30. The device of claim 1 wherein the at least one body is substantially cylindrical.

31. The device of claim 1 wherein the at least one body is has a substantially irregular shape.

32. The device of claim 1 wherein the at least one body is a biocompatible gel.

33. The device of claim 1 wherein the at least one body comprises a plurality of pores.

34. (amended) The device of claim 33 wherein the pores are configured to promote tissue growth in a preferred orientation.

35. The device of claim 1 wherein the at least one filler body additionally comprises a bio-compatible liquid.

36. A subcutaneous cavity marking device comprising a plurality of resilient bioabsorbable filler bodies, at least two of which are connected by at least one marker.

37. The device of claim 36 wherein the at least one marker is suspended through the interior of at least one of the plurality of filler bodies.

38. The device of claim 36 wherein the at least one marker is attached substantially to an outer perimeter of at least one of the plurality of bodies.

39. (amended) A method of marking a tissue cavity comprising the steps of:
(a) suspending a marker within at least one resilient bioabsorbable filler body, and
(b) inserting the at least one filler body into the cavity.

40. The method of claim 39 wherein the step of inserting the at least one filler body into the cavity is performed percutaneously.

41. The method of claim 40 wherein the at least one filler body additionally comprises a hemostatic substance.

42. The method of claim 40 wherein the at least one filler body additionally comprises a pain-killing substance.

43. The method of claim 40 wherein the marker is radiopaque.

44. The method of claim 40 wherein the marker is echogenic.

45. The method of claim 40 wherein the at least one body is radiopaque.

46. The method of claim 40 wherein the at least one body is echogenic.

47. The method of claim 40 wherein the marker is fixedly attached to the at least one body.

48. The method of claim 39 wherein the step of inserting the at least one filler body into the cavity is performed surgically.

49. The method of claim 39 wherein the step of inserting the at least one filler body of resilient bioabsorbable material into the cavity is performed prior to the step of suspending the marker within the filler body.

50. A method of marking a tissue cavity having a margin in a mammalian body, comprising:

(a) subcutaneously accessing the cavity via a delivery device,

(b) deploying a remotely detectable marker having a predetermined shape through the delivery device into the cavity,

wherein upon delivery into the cavity the marker assumes a predetermined three-dimensional configuration so to (1) substantially fill the cavity, (2) mark the cavity margin, and (3) indicate the orientation of the marker inside the cavity.

51. The method of claim 50 wherein the marker is bioabsorbable.

52. The method of claim 50 wherein the marker is radiopaque.

53. The method of claim 50 wherein the marker is echogenic.

54. The method of claim 50 wherein the marker comprises a wire.

55. The method of claim 50 wherein the marker comprises a material selected from the group consisting of platinum, iridium, nickel, tungsten, tantalum, gold, silver, rhodium, titanium, alloys thereof, and stainless steel.

56. The method of claim 50 wherein the marker is capable of emitting radioactive energy.

57. The method of claim 50 wherein the marker is a helical coil.

58. The method of claim 50 wherein the marker defines a volume having a substantially spherical shape when the marker is deployed inside the cavity.

59. The method of claim 50 wherein the marker defines a volume comprising a substantially cylindrical shape when the marker is deployed inside the cavity.

60. The method of claim 50 wherein the marker defines a volume comprising a random shape when the marker is deployed inside the cavity.

61. (amended) The method of claim 54 wherein the wire comprises a shape memory material.

62. The method of claim 50 further comprising the step of introducing a bio-compatible liquid in the marker prior to the step of deploying the marker.

63. The method of claim 62 wherein the delivery device uses a hydraulic force to deploy the marker.

64. The method of claim 50 further comprising the step of introducing a bio-compatible liquid in the marker subsequent to the step of deploying the marker.

65. The method of claim 64 wherein the bio-compatible liquid is introduced to the marker via the delivery device.

66. (new) A subcutaneous cavity marking device comprising:

(a) at least one resilient bioabsorbable filler body wherein said resilient bioabsorbable filler body comprises a palpable shell, wherein said shell is adapted to degrade when implanted within a patient's body, and wherein after said shell degrades said shell is no longer palpable, and

(b) at least one detectable marker attached to said filler body.

67. (new) The device of claim 66 wherein said shell is configured to degrade over a period of time.

68. (new) The device of claim 66 wherein said period of time is less than 1 year.

69. (new) The device of claim 67 wherein said period of time is between 2 and 6 months.

70. (new) The device of claim 67 wherein said period of time is about 3 months.

71. (new) The device of claim 13 wherein after insertion of said device into a patient said marker is not locatable by tactile detection.

72. (new) The device of claim 1 wherein after a period of time said body is not palpable.

73. (new) The device of claim 72 wherein said period of time is approximately 3 months.

74. (new) An implantable marking device comprising:

a resilient bioabsorbable body being palpable until at least partly absorbed within a patient's body, and

a permanently detectable marker within said bioabsorbable body, said marker being substantially nonpalpable after placement of the marking device in the patient's body.

75. (new) The method of claim 50 wherein the delivery device comprises a biopsy device.

76. (new) A subcutaneous cavity marking device comprising:

(a) at least one resilient filler body, and

(b) at least one detectable marker attached to said filler body wherein the marker has a configuration selected from the group consisting of a sphere, a ring, a band, a wire, a hollow sphere, and a barb.

77. (new) The device of claim 76 wherein the marker comprises a material selected from the group consisting of platinum, iridium, nickel, tungsten, tantalum, gold, silver, rhodium, titanium, alloys thereof, and stainless steel.

78. (new) The device of claim 76 wherein the at least one marker is radiopaque.

79. (new) The device of claim 76 wherein the at least one body is radiopaque.

80. (new) The device of claim 76 wherein the at least one marker is echogenic.

81. (new) The device of claim 76 wherein the at least one body is echogenic.

82. (new) The device of claim 76 wherein the at least one body is palpable.

83. (new) The device of claim 76 wherein the marker is located within an interior of the at least one body.

84. (new) The device of claim 76 wherein the marker is located at or near a geometric center of the at least one body.

85. (new) The device of claim 76 wherein the marker is within a geometric center of the at least one body.

86. (new) The device of claim 76 additionally comprising a pain killing substance.

87. (new) The device of claim 76 additionally comprising a hemostatic substance.

88. (new) The device of claim 76 wherein the filler body comprises a material selected from a group consisting of collagen, regenerated cellulose, synthetic polymers and synthetic proteins.

89. (new) The device of claim 76 wherein the marker has a form of a sphere.

90. (new) The device of claim 89 wherein the sphere is hollow.

91. (new) The device of claim 76 wherein the marker has a form of a band.

92. (new) The device of claim 76 wherein the marker comprises a suture.

93. (new) The device of claim 76 wherein the marker comprises a wire.

94. (new) The device of claim 76 wherein the marker has a distinguishing mark.

95. (new) The device of claim 76 wherein the marker is fixedly attached to the at least one body.

96. (new) The device of claim 95 wherein the marker is woven to the at least one body.

97. (new) The device of claim 76 wherein the marker is radioactive.

98. (new) The device of claim 76 wherein the at least one body is radioactive.

99. (new) The device of claim 76 wherein the at least one body is substantially spherical.

100. (new) The device of claim 76 wherein the at least one body is substantially cylindrical.

101. (new) The device of claim 76 wherein the at least one body is has a substantially irregular shape.

102. (new) The device of claim 76 wherein the at least one body is a biocompatible gel.

103. (new) The device of claim 76 wherein the at least one body comprises a plurality of pores.

104. (new) The device of claim 103 wherein the pores are configured to promote tissue growth in a preferred orientation.

105. (new) The device of claim 76 wherein the at least one body additionally comprises a bio-compatible liquid.

106. (new) The device of claim 76 wherein the at least detectable marker comprises a non-bioabsorbable material.

107. (new) The device of claim 76 wherein the at least detectable marker comprises a bioabsorbable material.

108. (new) The device of claim 76 wherein the at least one filler body comprises a bioabsorbable material.

REMARKS

The present case is a continuation of U.S. Serial No. 09/285,329 (hereinafter referred to as the 'parent' case.) In the parent case, an Office Action (mailed December 20, 2000) 'objected to' certain claims and rejected others. In the parent case, applicants chose to place the 'objected to' claims in condition for allowance. Applicants now seek to address the outstanding previous rejections in this continuation. Accordingly, applicants now address the rejections from the previously mentioned Office Action. Claims 1-108 are pending in the application.

35 USC §112

Applicants note that claim 34 was previously submitted in U.S. Patent Application Serial No. 09/285,329, and was rejected under 35 USC §112 because of insufficient antecedent basis for the limitation of "the pores" in line 1. Claim 34 has been amended accordingly to provide the proper antecedent basis.

CLAIM REJECTIONS - 35 USC §102

Pathak et al. (5,662,712)

In U.S. Patent Application Serial No. 09/285,329, the parent to this application, an Office Action rejected claims 1-3, 28-31, 33, 34, 50, and 55 (as numbered in the parent application) under 35 USC §102(b) as being anticipated by Pathak et al. Pathak et al. fails to anticipate the claims of the present invention.

Applicants have amended claim 1 to more clearly recite applicants' invention. Pathak et al. fails to contain any teaching or suggestion that limits the location of the marker to at or near the center of the filler body. Accordingly, Pathak et al. fails to anticipate currently pending claim 1 and all claims dependent therefrom.

Furthermore, Pathak et al. fails to disclose or suggest, deploying a remotely detectable marker into a cavity whereupon delivery into the cavity, the marker assumes a predetermined

three dimensional configuration. Accordingly, Pathak et al. fails to anticipate claim 50 and all claims dependent therefrom.

Regarding newly added claim 77 and all claims dependent therefrom, Pathak et al. fails to teach a subcutaneous cavity marking device comprising at least one resilient filler body, and at least one detectable marker attached to said filler body wherein the marker has a configuration selected from the group consisting of a sphere, a ring, a band, a wire, a hollow sphere, and a barb.

Ragheb et al. (5,873,904)

In U.S. Patent Application Serial No. 09/285,329, the parent to this application, an Office Action rejected claims 1-6, 9, 10, 27, 28, 44, 46, 50, 53, 56, and 61, (as numbered in the parent application) under 35 USC §102(e) as being anticipated by Ragheb et al. Applicants disagree.

Ragheb et al. fails to contain any teaching or suggestion that limits the location of the marker relative to the filler body. Accordingly, Ragheb et al. fails to anticipate currently pending claim 1 and all claims dependent therefrom.

Nowhere does Ragheb et al. teach this specific combination. Relying upon Ragheb et al. to teach a device having a bioabsorbable filler body with a non-bioabsorbable marker creates undesirable combination which creates a risk of releasing the non-bioabsorbable marker within the body once the bioerodable polymeric material dissolves. Such a device is clearly not suited for use as a vascular stent such as that disclosed by Ragheb et al.

Furthermore, Ragheb et al. does not teach, show, or suggest "suspending a marker within at least one resilient bioabsorbable filler body" as required by claim 39 from which claims 44 and 46 of the present invention depend.

Furthermore, it is submitted that Ragheb et al. does not teach, show, or suggest deploying a marker through a delivery device as required by claim 50 from which claims 53, 56, and 61 of the present invention depend. Among Ragheb et al.'s teachings are a "balloon expandable stent . . . formed from a single strand of cylindrical stainless steel wire" (column 22, lines 16-18), a

"self-expanding stent . . . formed from cylindrical wire" (column 23, line 51), and a stent "formed from a tube of stainless steel material with a plurality of slits 55 cut in the tubular wall. This stent is delivered on a balloon catheter and expanded at the desired vascular site." (column 24, lines 7-10)

Regarding newly added claim 77 and all claims dependent therefrom, Ragheb et al. fails to teach a subcutaneous cavity marking device comprising at least one resilient filler body, and at least one detectable marker attached to said filler body wherein the marker has a configuration selected from the group consisting of a sphere, a ring, a band, a wire, a hollow sphere, and a barb.

Wolff et al. (5,871,535)

In U.S. Patent Application Serial No. 09/285,329, the parent to this application, an Office Action rejected claims 1, 7, 8, 13, 14, 16-18, 21-26, 36, 39-43, 45, 47, 50, 51, 52, 54, and 66 (as numbered in the parent application) under 35 USC §102(e) as being anticipated by Wolff et al. Applicants disagree.

Wolff et al. fails to contain any teaching or suggestion that limits the location of the marker relative to the filler body. Accordingly, Ragheb et al. fails to anticipate currently pending claim 1 and all claims dependent therefrom.

Regarding newly added claim 77 and all claims dependent therefrom, Wolff et al. fails to teach a subcutaneous cavity marking device comprising at least one resilient filler body and at least one detectable marker attached to said filler body wherein the marker has a configuration selected from the group consisting of a sphere, a ring, a band, a wire, a hollow sphere, and a barb. Moreover, given a reading of Wolff et al. it would not be apparent to one skilled in the art to make a combination as the invention of claim 77. Wolff et al. teaches the use of the marker bands "to locate the stent and assure proper placement and patency" as opposed to depositing the marker within the center of a cavity. Wolff et al. never teaches the specific combination of elements of claim 77 of applicants' invention. The suggestion that the teachings of Wolff et al.

anticipate claim 77 appears to rely upon impermissible hindsight given applicants' claim and specification.

CLAIM REJECTIONS - 35 USC §103

Wolff et al. (5,871,535)

In U.S. Patent Application Serial No. 09/285,329, the parent to this application, an Office Action rejected claims 15, 19, 20, 29-31, 37, 38, 49, and 57-60 (as numbered in the parent application) under 35 USC §103(a) as being unpatentable over Wolff et al.

The Office Action provided the above rejection of applicants' claims arguing that "it would have been a matter of design choice to one having ordinary skill in the art at the time the invention was made." Applicants strongly disagree. It is respectfully submitted that the Office Action failed to establish a *prima facie* case of obviousness.

First, applicant refers to the M.P.E.P. §2143.01, which provides, in part, that it is insufficient to merely state that it is within the ordinary skill of the art to modify a reference to meet the claimed invention. Such a statement is not enough to establish a *prima facie* case of obviousness without some objective reason to combine or modify the teachings of the reference. Applicants note that the prosthesis of Wolff et al. limits restenosis of a lumen. Accordingly, the Office Action failed to provide any objective reasons as to why one would want to modify the Wolff prosthesis to include, for example: a marker located within a geometric center of the prosthesis (pending claim 1); a marker in the form of a sphere or hollow sphere (claim 19-20); a substantially spherical body (claim 29); or a substantially irregular shaped body (claim 31).

Applicants further note that the M.P.E.P. section cited above provides that a proposed modification cannot render the prior art unsatisfactory for its intended purpose. Clearly, making any of the modifications discussed above will render the Wolff prosthesis unsuitable for limiting the restenosis of a lumen.

More specifically, if the Wolff prosthesis contains a marker within the geometric center of the body (as in amended claim 1) the modified prosthesis will contain an occluded lumen.

The invention of Wolff et al. "is related to methods for lessening restenosis of body lumens, and to prosthesis for delivering drugs to treat said restenosis" (column 1, lines 13-15). "The prosthesis comprises a generally flexible tubular body which is fixed against the lumen walls by a mechanical action. The device should not cause an appreciable reduction in the lumen cross-section where inserted" (column 2, lines 8-11). Given the explicit teaching of Wolf et al., modifying the Wolf prosthesis to contain a marker in its geometric center renders the modified prosthesis unsatisfactory for its intended purpose.

Accordingly, applicants believe the previous rejection is improper.

Wolff et al. (5,871,535) in view of Davidson (6,057,122)

In U.S. Patent Application Serial No. 09/285,329, the parent to this application, an Office Action rejected claims 32 and 35 (as numbered in the parent application) under 35 USC §103(a) as being unpatentable over Wolff et al. in view of Davidson.

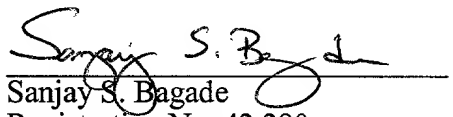
Applicants disagree with this rejection. Applicants note that Wolff et al. fails anticipate claim 1. Since Davidson does nothing to remedy the defects of Wolff et al., applicants believe this rejection is in error.

CONCLUSION

Basis for the above amendments and added claims are found in the specification. No new matter is being added. The amendments to the specification are corrections of typographical errors. Should the Examiner have any questions, a call to applicant's attorney at the number listed below will be appreciated.

Respectfully submitted,

Dated: March 13, 2001

By: 

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Examiner: To Be Assigned

Group Art Unit: To Be Assigned

REWRITTEN CLAIMS ACCOMPANYING PRELIMINARY AMENDMENT

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Included herein is a version of the claims in the accompanying preliminary amendment, that are re-written. The changes to the claims are as indicated.

1. (amended) A subcutaneous cavity marking device comprising:

[(a) at least one filler body comprising a resilient bioabsorbable material, and

(b) at least one marker.]

(a) at least one resilient bioabsorbable filler body, and

(b) at least one detectable marker attached to said filler body, wherein at least one of said detectable markers is located at or near a geometric center of said filler body.

4. (amended) The device of claim 1 wherein the at least one marker comprises a [second] bioabsorbable material.

5. (amended) The device of claim 4 wherein the [second] bioabsorbable material comprises a polymer having a radiopaque additive.

18. (amended) The device of claim 1 wherein the bioabsorbable filler body comprises a material [is] selected from the group consisting of collagen, regenerated cellulose, synthetic polymers, and synthetic proteins.

34. (amended) The device of claim 33 [1] wherein the pores are configured to promote tissue growth in a preferred orientation.

39. (amended) A method of marking a tissue cavity comprising the steps of:
(a) suspending a marker within at least one [filler body of] resilient bioabsorbable [material] filler body, and
(b) inserting the at least one filler body into the cavity.

61. (amended) The method of claim [50] 54 wherein the wire comprises a shape memory material.

Respectfully submitted,

Dated: March 13, 2001

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